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| 10/772,963 | 02/05/2004 | David P. Bingaman | 2471 US | 5299 |

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| EXAMINER | |
|---|---|
| HUI, SAN MING R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/772,963 | BINGAMAN ET AL. | |
| | Examiner | Art Unit | |
| | San-ming Hui | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendments filed November 15, 2005 have been entered. Claims 1-18 are pending.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman et al. (US patent 5,516,522) and Clark, Clark is reference of record.

Peyman teaches prednisolone, prednisolone acetate, triamcinolne, fluoromethalone, and fluoromethalone acetate as useful in treating proliferative vitreoretinopathy (PVR), an ocular angiogenesis-associated disorder (See col. 7, lines 33-55, especially lines 50, 51, 54). Peyman also teaches the ocular formulation may be as intraocular implant (See the abstract and claim 1).

Clark teaches anecortave acetate as useful in treating ocular neovascularization condition (See claims 1-5). Clark also teaches the composition can be formulated and administered as intraocular injection (See col. 4, lines 50).

The references taken together do not expressly teach the incorporation of both the herein claimed steroids and anecortave acetate together in a method of treating angiogenesis disorder such as PVR. The references taken together do not expressly teach the herein claimed dosages.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the herein claimed steroids and anecortave acetate together in a method of treating angiogenesis disorder such as PVR. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed dosage to treat PVR.

One of ordinary skill in the art would have been motivated to incorporate the herein claimed steroids and anecortave acetate together in a method of treating angiogenesis disorder such as PVR since the agents are well-known to be useful in treating PVR or neovascularization individually. Therefore, concomitantly employing both agents in a method for the same indications would be *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Furthermore, one of ordinary skill in the art would have been motivated to employ the herein claimed dosage to treat PVR since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Claims 1-2, 4-5, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/03807('807) and Clark.

'807 teaches a method of treating neovascular macular degeneration, an ocular angiogenesis disorder, by administration of triamcinolne (See the abstract, claims 22-25). '807 teaches the routes of administration may be intravitreal injection (See page 3, lines 19-25).

Clark teaches anecortave acetate as useful in treating ocular neovascularization condition (See claims 1-5). Clark also teaches the composition can be formulated and administered as intraocular injection (See col. 4, lines 50).

The references taken together do not expressly teach the incorporation of both the triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder such as neovascular macular degeneration. The references taken together do not expressly teach the herein claimed dosages.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder such as neovascular macular degeneration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed dosage to treat neovascular macular degeneration.

One of ordinary skill in the art would have been motivated to incorporate triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder such as neovascular macular degeneration since the agents are well-known to be useful in treating neovascular macular degeneration individually. Therefore, concomitantly employing both agents in a method for the same indications would be *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Furthermore, one of ordinary skill in the art would have been motivated to employ the herein claimed dosage to treat neovascular macular degeneration since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark and US 4,686,214 ('214).

Clark teaches anecortave acetate as useful in treating ocular neovascularization inflammatory condition (See claims 1-5). Clark also teaches the composition can be formulated and administered as intraocular injection (See col. 4, lines 50).

'214 teaches rimexolone as useful in treating ocular inflammation (See claim 2). The effective dosage of rimexolone taught as 0.05 to 2.0% (See col. 2, line 59-60).

The references taken together do not expressly teach the incorporation of both rimexolone and anecortave acetate together in a method of treating angiogenesis inflammatory disorder. The references taken together do not expressly teach the herein claimed dosages.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to the incorporation of both rimexolone and anecortave acetate together in a method of treating angiogenesis inflammatory disorder. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed dosage to treat angiogenesis inflammatory disorder.

One of ordinary skill in the art would have been motivated to the incorporation of both rimexolone and anecortave acetate together in a method of treating angiogenesis inflammatory disorder since the agents are well-known to be useful in treating ocular inflammation individually. Therefore, concomitantly employing both agents in a method

for treating ocular inflammation associated with angiogenesis would be *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Furthermore, one of ordinary skill in the art would have been motivated to employ the herein claimed dosage to treat ocular inflammation associated with angiogenesis since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

***Response to Arguments***

Applicant's arguments filed November 15, 2005 averring the cited prior arts' failure to teach or provide motivation to employ both agents to treat proliferative vitreoretinopathy have been fully considered but they are not persuasive. The basis to combine them in a method of treating PVR is based on the fact that the herein recited compounds are known to be effective in treating PVR individually. Therefore, absent evidence to the contrary, it flows logically to employ them together for the method of treating the very same disorder (See *Kerkhoven* supra). At least additive effect would be expected.

Applicant's arguments filed November 15, 2005 with regard to dosage determination have been considered, but are not found persuasive. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infection would require a correspondingly

higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to employ various dosages of the same actives or combination of agents to achieve the optimal effects. Such optimization of dosage regimen is routinely done in almost every patient and thus, obvious to one of ordinary skill in the art, absent evidence to the contrary.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617